Standards and Calibration Laboratory

Quality Assurance Program Plan

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Introduction

The Standards and Calibration Laboratory (S&CL), organized as a team within the Engineering Sciences and Applications Division's Measurement Technology Group, is the Laboratory's central facility for maintaining measurement traceability to national standards in the areas of dimensional, physical, and electrical measurement. Dimensional areas include length, angle, flatness, parallelism, roundness, surface finish, and force. Physical areas include mass, pressure, gas flow, temperature, density, torque, and vibration. Electrical areas include current, voltage, resistance, capacitance, inductance, power, attenuation, waveform analysis, time, and frequency. All equipment and measurement standards used to perform traceable calibrations are listed in a metrology database maintained by the S&CL.

Quality Policy Statement

The Standards and Calibration Laboratory will operate in accordance with the requirements of the following documents:

1. ANSI/ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities."

2. ANSI/NCSL Z540-1-1994, "American National Standard for Calibration."

3. NIST Handbook 150, "National Voluntary Laboratory Accreditation Program: Procedures and General Requirements."

The format of this Quality Assurance Program Plan follows that of NQA-1, with each of the eighteen points being addressed.

1.0 Organization

1.1 Organization Charts

Organization charts for the Standards and Calibration Laboratory and its parent organizations leading up to the Laboratory director are shown in Appendix 1.

1.2 Responsibilities

Many personnel share in the development and implementation of the quality assurance program, and all members of the team are responsible for complying with its requirements. The following is a brief description of each employee's responsibilities in the quality program.

- The team leader serves as both the technical manager with overall responsibility for technical operations and the quality manager, with responsibility for the quality system and its implementation.

- The unit leaders serve as the technical leaders of their respective sections and are responsible for assuring that employees in their section comply with the requirements of the quality system.

- The test/measurement technicians in each section perform calibrations, maintain and develop their areas, originate most procedures and dataforms, and train other employees. They are responsible for advancing their technical knowledge and maintaining their qualification in the areas in which they work, and for understanding and complying with the requirements of the quality system that pertain to their work.

- The quality assurance specialist reviews all calibration reports, procedures, dataforms, and software generated by the team for accuracy and conformance with specifications. This individual also scans calibration report packages into the image database, and controls the archive copies of all quality program documents.

- The programmer/quality assurance officer maintains and develops the metrology database, network, and image database, and oversees the quality review process.

- The administrative assistant receives and disburses equipment, assigns file numbers and records customer requirements, answers questions related to the Laboratory calibration program or S&CL services, and provides administrative support to team members.

- The pickup and delivery representative picks up and delivers customer equipment for calibration.

2.0 Quality Assurance Program

2.1 Laboratory Calibration Program

The Laboratory's policy on calibration and instructions for its implementation are described in LALP-93-47 *Calibration Handbook*.

2.2 S&CL Quality Assurance Program

The Standards and Calibration Laboratory quality assurance program is described in the following planning documents.

SCL-PD-0001 *Quality Assurance Program Plan* describes the overall quality assurance program.

SCL-PD-0002 *Calibration Process Manual* describes the general requirements for performing and documenting calibrations.

SCL-PD-0003 *Document Control* describes the requirements for the preparation, identification, review, approval, distribution, revision, and control of quality-affecting documents.

SCL-PD-0005 *Environmental Controls* describes the controls on the physical environment in which calibrations are performed.

SCL-PD-0006 *Software* describes the requirements for the preparation, identification, review, approval, revision, and control of software originated by the Standards and Calibration Laboratory.

SCL-PD-0007 *Records* describes the requirements for the retention and storage of records.

SCL-PD-0008 *Training and Qualification* describes the methods used to ensure that personnel are adequately trained.

SCL-PD-0010 *Calibration Intervals* describes the categories into which equipment is classified and lists the calibration interval assigned to each category.

SCL-PD-0011 *Metrology Database System Manager's Manual* describes the design of the metrology database and provides guidance for the system manager.

SCL-PD-0013 *Quality Assurance Review* contains the standards used by the quality assurance specialist to review report packages.

SCL-PD-0014 *Image Database Scanning Procedure* contains instructions for individuals who scan documents into the image database.

SCL-PD-0015 *Complaints* describes the procedures used to resolve complaints received from customers or other parties about Standards and Calibration Laboratory activities.

SCL-PD-0016 *Internal Audits* describes the methods by which the Standards and Calibration Laboratory reviews and audits its own operations.

SCL-PD-0017 *Equipment Maintenance* describes the maintenance procedures required for Standards and Calibration Laboratory equipment.

3.0 Design Control

Because the Standards and Calibration Laboratory does not do design work, formal design control procedures are not required.

4.0 Procurement Document Control

4.1 Purchases Using Operating Funds

Purchase requests for measuring and test equipment that will be acquired using operating funds are prioritized and reviewed for technical content by a panel that includes a member of each section of the team, and are approved by the team leader or designee before being issued.

4.2 Purchases Using Capital Funds

Requests for capital equipment are prioritized and reviewed for technical content by the unit leaders and team leader, and are submitted annually for inclusion in the ESA Division capital equipment request. Upon receipt of funding for capital items, the requestor drafts appropriate procurement documents, which are reviewed for technical content by the team leader or designee before being issued.

5.0 Instructions, Procedures, and Drawings

5.1 Planning Documents

The planning documents listed in Section 2.0 constitute the instructions for activities affecting quality. Additional instructions or changes to instructions are issued in the form of Documentation Memos, which are controlled as quality program documents. These memos are closed out by incorporating them into one of the planning documents as soon after their issue as practical.

5.2 Calibration Procedure Libraries

Calibration procedure libraries are maintained to provide guidance for the individual performing a calibration. These libraries include procedures from the Government-Industry Data Exchange Program operated by the Department of Defense, the Air Force calibration program, and manufacturers' literature. Federal specifications for selected instruments are also kept on file. Because equipment differences and other factors may not permit strict adherence to some of these procedures, the person performing the calibration may deviate from them based upon his or her judgement. However, each calibration must be documented in sufficient detail that another person familiar with the discipline could, using the information in the calibration package, reconstruct the method used to perform it.

5.3 S&CL Procedures and Dataforms

When time permits, calibration methods are documented in approved Standards and Calibration Laboratory procedures and dataforms. Because these procedures and dataforms are specific to the Standards and Calibration Laboratory, strict adherence is required except in rare instances such as an equipment failure where such adherence is impossible. In such cases, any deviation is described in detail in the report package for the calibration.

6.0 Document Control

6.1 Document Control Procedure

Requirements for the preparation, identification, review, approval, distribution, revision, and control of quality-affecting documents are contained in SCL-PD-0003, *Document Control Procedure*.

6.2 Confidentiality of Documents

Because Los Alamos National Laboratory is a government-owned facility and the work performed by the Standards and Calibration Laboratory is unclassified, all documentation produced by the team, including records of individual calibrations, are considered to be non-confidential and in the public domain.

7.0 Control of Purchased Items and Services

7.1 Control of Purchased Items

The accuracy and functionality of purchased items can affect the quality of the calibration process. However, because every parameter that has an effect on quality is calibrated either before or during the calibration of customer equipment, no additional control is considered necessary.

7.2 Control of Purchased Calibration Services

The Standards and Calibration Laboratory procures calibration services only from the National Institute of Standards and Technology or standards laboratories within the Department of Energy nuclear weapons complex. Because the National Institute of Standards and Technology represents the nation's highest standards organization and the weapons complex laboratories are periodically audited by the Department of Energy, no additional quality requirements are placed on purchases from these sources.

8.0 Identification and Control of Items

8.1 Identification of Items Received for Calibration

Items received for calibration are assigned a unique file number upon arrival at the Standards and Calibration Laboratory. A tag is attached to each item to identify it and to record any special requirements specified by the customer. SCL-PD-0002, *Calibration Process Manual* describes this process and the methods used for subsequent scheduling and routing of the item.

8.2 Calibration Labels

Upon completion of a calibration, the status of the item is identified by a calibration label bearing the file number and other information, which is attached to the instrument prior to its release to the customer. Calibration labels are described in SCL-PD-0002, *Calibration Process Manual*.

9.0 Control of Processes

9.1 Personnel Training and Qualification

All personnel must be trained and qualified prior to performing quality-affecting work, or must be overseen by an employee with the proper training and qualification. Training and qualification requirements are described in SCL-PD-0008, *Training and Qualification.*

9.2 Approved Signatories

Upon completion of each calibration, an approved signatory must sign the history sheet to verify that the calibration has been performed correctly. The list of approved signatories for each type of measurement is maintained in the metrology database and in hard copy form by the team leader. Further information is contained in SCL-PD-0008, *Training and Qualification*.

9.3 Requirements for Performing and Documenting Calibrations

General requirements for performing and documenting calibrations are specified in SCL-PD-0002, *Calibration Process Manual*.

9.4 Control of Calibration Software

Computer software used to perform calibrations or reduce calibration data is controlled as described in SCL-PD-0006, *Software*.

9.5 Control of Environment

Environmental controls are described in SCL-PD-0005, *Environmental Controls*. This document also describes the steps to be taken when the environment is not within its specified limits.

10.0 Inspection

Control over the consistency and accuracy of calibration documentation is provided by the quality assurance specialist, who reviews every report package prior to its release. Criteria for this review process are described in SCL-PD-0013, *Quality Assurance Review*. Additional verifications are built into the metrology database, which is controlled by the programmer/quality assurance officer.

11.0 Test Control

Measurements of items that are neither standards nor measuring equipment are conducted as special tests. The requirements for conducting and documenting special tests are contained in SCL-PD-0002, *Calibration Process Manual*. Special test reports are reviewed in the same manner as

calibration reports.

12.0 Control of Measuring and Test Equipment

12.1 Calibration of Equipment

All equipment that affects the accuracy of the calibration process is calibrated prior to use, either on a regularly scheduled basis or at the time of use.

12.2 Calibration Intervals

Calibration intervals are specified in SCL-PD-0010, Calibration Intervals. These intervals are originally established on the basis of subjective experience, which includes consideration of the interval assigned by other standards laboratories. When sufficient data exists, intervals are reevaluated to achieve 95% confidence that an item will remain within its specified tolerance or uncertainty limits at the end of its calibration interval. Calibration intervals are reviewed at least every five years.

12.3 Recall Notices

In the month preceding the expiration of a calibration, a recall notice is generated by the Metrology Database and sent to the contact of record. It is the responsibility of the contact to determine whether the item should be recalibrated.

12.4 Equipment Maintenance

In order to assure operability, measuring equipment is maintained according to the procedures described in SCL-PD-0016, *Equipment Maintenance*.

13.0 Handling, Storage, and Shipping

13.1 Equipment Room

Items that are being held prior to calibration or after calibration but prior to release are stored in an equipment room that is locked except during normal business hours.

13.2 Laboratory Areas

To protect the equipment owned by the Standards and Calibration Laboratory as well as that owned by its customers, all laboratory areas are locked except during normal business hours.

13.3 Pickup and Delivery

Personnel who pickup and deliver items are trained regarding the handling of sensitive equipment.

13.4 Shipment to Off-Site Locations

Unit leaders are responsible for ensuring that equipment that must be shipped off site is packaged appropriately to prevent damage. When necessary, equipment may be hand-carried to prevent damage.

14.0 Inspection, Test, and Operating Status

The calibration status of all standards and measuring equipment owned by the Standards and Calibration Laboratory, including items that do not require calibration, is indicated by a calibration label placed on or near the item. In addition, the metrology database verifies that all items entered as standards are currently in calibration.

15.0 Control of Nonconforming Items

15.1 Calibration Report Packages

Calibration report packages that do not meet requirements are returned by the quality assurance specialist to the originator for correction.

15.2 Out-Of-Tolerance Conditions

The as-received condition of items submitted for calibration is measured prior to making adjustments. If an item is found to be outside its expected tolerance or uncertainty limits during this test, the contact is notified as described in SCL-PD-0002, *Calibration Process Manual*.

15.3 Limited Calibrations

When an item submitted for calibration is deemed by the person performing the calibration to be usable, but it cannot be adjusted to within normal tolerance limits, the calibration is designated as a Limited calibration. Limited calibrations are identified by use of a Certification Limited label, and the limitations are noted on the label and in the calibration certificate. Limited calibrations are described in SCL-PD-0002, *Calibration Process Manual*.

15.4 Rejected Items

When an item submitted for calibration is found to be inoperative or outside usable tolerance limits, it is rejected. A rejected item is identified by a Rejected label, and the reason for rejection is described in a Rejected report. Rejections are described in SCL-PD-0002, *Calibration Process Manual*. Final disposition of a rejected item is the responsibility of the owning organization. In the case of items owned by the Standards and Calibration Laboratory, use of the item is immediately discontinued, and it is either repaired, recalibrated, and returned to service, or discarded at the earliest opportunity.

15.5 Compliants

SCL-PD-0014 *Complaints* describes the procedures used to resolve complaints received from customers or other parties about Standards and Calibration Laboratory activities.

16.0 Corrective Action

16.1 Audits or Surveys

Conditions adverse to quality that are identified during audits or surveys and the planned corrective action are documented by the team leader. Corrective action may include issuing new or revised operating procedures, implementing appropriate training, or other measures.

16.2 Report Packages

If errors are found in report packages after the calibration report has been issued, they are corrected by issuing an amendment. The requirements for amendments are specified in SCL-PD-0002, *Calibration Process Manual*.

17.0 Quality Assurance Records

17.1 Record Procedure

Records that document the quality system and the results of measurements performed by the Standards and Calibration Laboratory include planning documents, calibration procedures, dataforms, calibration software, personnel training and qualification records, audit reports, documentation memos, and calibration report packages. These records are controlled in accordance with SCL-PD-0007, *Records*.

17.2 Metrology Database

Much of the important information regarding a calibration and its traceability is contained in the metrology database. This database is backed up daily to a secondary computer and a tape drive. In addition, two archive backup tapes are recorded each month. One is retained in the team's computer room and the other is sent to the Laboratory records center. Database information is also maintained in hard copy form on the history sheet in each calibration report package.

17.3 Image Database

Before filing completed report packages, the quality assurance specialist scans them into an image database. The use, maintenance, and archiving of this database is described in SCL-PD-0014 *Image Database Scanning Procedure*.

18.0 Audits

18.1 Internal Audit Program

In order to assure a continued high level of quality, the Standards and Calibration Laboratory conducts a continuing self-examination process that includes an annual review of all quality system documents and surveys and audits conducted by agencies internal and external to the Laboratory. This program is described in SCL-PD-0015 *Internal Audits*.

18.2 Additional Audits

Additional audits by agencies internal or external to the Laboratory may be conducted with proper authorization.

APPENDIX 1: ORGANIZATION CHART

Shown below is the direct reporting chain between the Standards and Calibration Laboratory and the Laboratory Director. More detailed Laboratory organization charts are available on the Los Alamos National Laboratory home page.

LOS ALAMOS NATIONAL LABORATORY

Laboratory Director
John C. Browne

Associate Laboratory Director for Nuclear Weapons
Stephen M. Younger

Engineering Sciences and Applications Division
John J. Ruminer (Acting)

Measurement Technology Group
Paul A. Smith

Standards and Calibration Laboratory
Allen L. Gauler